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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,178	09/25/2001	Robert Raffa	TUN-566US	9598

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EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/964,178	RAFFA ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,11,12 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,11,12 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/24/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 3, 2004 has been entered.

Applicant has submitted preliminary remarks/arguments with the RCE. In these remarks, Applicant discusses the difference between acute and chronic pain. Applicant further states that "the present invention addresses the treatment or alleviation of pain, but not necessarily treatment of the underlying condition which is the cause of the pain."

These remarks are noted, but Office personnel are to give claims their broadest reasonable interpretation in light of and consistent with the supporting disclosure. However, limitations appearing in the specification or Applicant's arguments but not recited in the claim are not read into the claim. It is further noted that the disclosure specifically suggests the treatment of pain that would be considered acute (toothache) and chronic (arthritis). See page 4, lines 15-17. Furthermore, the disclosure suggests that an advantage of the present invention is to allow for lower dosages of analgesics with undiminished pain relief because "it is also known that the *daily consumption* of non-opioid analgesics, either alone or in combination, in large amounts or *over time* also poses health risks. (Emphasis added) See discussion at pages 1-3.

Claim Rejections - 35 USC § 112

Claims 1-6, 11, 12, and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "the glucosamine material is α– or β–glucosamine or mixtures thereof, N-acetyl glucosamine, glucosamine sulfate, or glucosamine hydrochloride . . ." Read in light of the specification (see page 4, lines 18-29) it would appear that this claim is to be interpreted as "the glucosamine material is *selected from the group consisting of* α– or β–glucosamine or mixtures thereof, N-acetyl glucosamine, glucosamine sulfate, or glucosamine hydrochloride . . ." Claim 16 ultimately depends from claim 1 but recites "the glucosamine material *comprises* α– or β–glucosamine, N-acetylglucosamine, glucosamine sulfate, or glucosamine HCl . . ." (emphasis added) Because of this more open language in the dependent claim, it is not clear that the examiner's original interpretation of claim 1 is correct. Further, it is not clear as to the metes and bounds of what is allowed for the "glucosamine material": (1) the particular recited glucosamines; (2) any monomeric glucosamine; (3) any glucosamine-containing material, such as glycosaminoglycans (GAGs); (4) something else. The claims are thus rendered vague and indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by MEISSNER (US 4,772,591).

MEISSNER discloses the administration of glucosamine and Nalfon (fenoprofen) for the treatment of pain associated with osteoarthritis. See example 11. Assuming a woman of average weight, the disclosed dosage would fall into the range recited in claim 15.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by FALK (US 5,811,410).

FALK discloses compositions comprising NSAIDs and hyaluronic acid. See cases XX and XXI, for example. The examiner notes that the dosage formulas are not actually administered orally, but there is nothing to preclude such adminstration.

Claims 1, 2, 14, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by HAMMERLY (US 6,608,041).

HAMMERLY discloses several compositions comprising glucosamines and analgesics having the recited weight ratios. See Examples 7, 8, and 11-14. The reference further teaches the use of these compositions for pain relief. See col 4, lines 20-34.

Claim Rejections - 35 USC § 103

Claims 1-4, 12, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over MEISSNER (US 4,772,591).

MEISSNER teaches as set forth above. The reference does not exemplify other components recited in claim 12.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare a composition taught by MEISSNER and modify it with the addition of another component, such as an antiarthritic. The reference teaches that the composition has utility for the treatment of arthritis, so the artisan would be motivated to add an antiarthritic for the additive effects. It would further be within the scope of the practitioner to add other components for the treatment of a patient having multiple symptoms. One of ordinary skill would optimize dosages through routine experimentation. The practitioner would reasonably expect success in making such modifications.

Claims 1-6, 11, 12, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over FALK (US 5,811,410) and ROENTSCH et al (US 5,654,337).

FALK teaches as set forth above. The reference further teaches the use of these compositions for a variety of symptoms, such as back pain, with ibuprofen. See the Table bridging col 19-20. The reference further teaches that the disclosed compositions may be administered by any common method, such as orally. See col 10, lines 37-40. The reference does not exemplify oral administration, propionic acid analgesics, or other components recited in claim 12.

ROENTSCH teaches that ibuprofen and ketoprofen are functional equivalents in the treatment of pain and have utility in combination with muscle relaxants. See col 1, lines 7-21.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare a composition comprising any of the recited propionic acid analgesics for oral administration taught by FALK and modify it with the addition of another component, such as a muscle relaxant. The reference teaches that the composition has utility for the treatment of muscular discomfort, such as back pain, so the artisan would be motivated to add a muscle relaxant for the additive effects. It would further be within the scope of the practitioner to add other components for the treatment of a patient having multiple symptoms. One of ordinary skill would optimize dosages through routine experimentation. The practitioner would reasonably expect success in making such modifications.

Allowable Subject Matter

The specification appears to disclose a synergistic effect for the combination of ibuprofen and ketoprofen in combination with the monomeric glucosamine species recited in the claims. Claim 16, limited to these monomeric species, written in independent form, incorporating all the limitations of the base claim and any intervening claims. Similarly limited compositions would also be allowable.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier

Leigh C. Maier
Patent Examiner
July 12, 2004